

### **REMARKS**

The present Office Action addresses and rejects claims 1, 4-35, and 56-63. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

At the outset, Applicants thank Examiner Yang for extending the courtesy of a telephone interview to Applicants' undersigned representative and for agreeing to review proposed claim amendments.

#### ***Amendments to the Specification***

Applicants amend the specification to correct typographical errors. No new matter is added.

#### ***Amendments to the Claims***

Claims 1, 56, 57, 59, and 60 have been amended to more particularly point out and distinctly claim the present invention. These amendments do not encompass new subject matter and do not require an additional subject matter search. As such, Applicants respectfully request that the claims as amended be entered for examination pursuant to MPEP §§ 714.12-13. Applicants consider that in view of these amendments and the arguments set forth below, the application is in condition for allowance. In the alternative, if the claims are not found to be in condition for allowance, the amendments would place the claims in better condition for appeal.

Independent claims 1 and 56 are amended to recite bone anchors having a bone-engaging portion and a receiving portion with opposed arms that receive a rod (claim 1) or fixation element (claim 56) therebetween. Claims 1 and 56 are further amended to recite a rod or fixation element disposable between the opposed arms of the receiving portion of the bone anchors and to recite a connecting plate having a distal surface that bears against a proximal terminal end surface of the opposed arms of the receiving portion of the bone anchor(s). Claim 56 is also amended to include the limitations of claim 58, and in particular to recite a closure mechanism extending through the connecting plate and engaging one of the bone anchors to fix the fixation element within the bone anchor. Claim 57 is amended to clarify that it is the bone-engaging portion of the bone anchor that includes a bone screw portion and a head. Claim 58 is cancelled and claim 59 is amended to now depend from claim 57. Claim 60 is amended to

recite the step of positioning a distal surface of a connecting plate on a proximal terminal end surface of opposed arms of a rod receiving portion of the first bone anchor by inserting a closure mechanism through the connecting plate to engage the rod receiving portion. Support for these amendments can be found throughout the specification and the drawings. No new matter is added.

***Claim Rejections Pursuant to 35 U.S.C. § 102(b)***

Claims 1, 17-20, 29, 56, and 60-63 are rejected pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,397,363 ("Gelbard"). Applicants respectfully disagree.

***Claim 1***

Amended independent claim 1 recites a spinal fixation system that includes at least two bone anchors having a bone-engaging portion and a rod receiving portion with opposed arms that receive a rod therebetween. The system also includes a rod disposable between the opposed arms of the rod receiving portion of the at least two bone anchors for connecting the bone anchors. The system also includes a connecting plate having a distal surface that bears against a proximal terminal end surface of the opposed arms of the rod receiving portion of at least one of the bone anchors.

Gelbard fails to teach or even suggest the claimed system because it lacks a connecting plate with a distal surface that bears against a proximal terminal end surface of the opposed arms of the rod receiving portion of at least one of the bone anchors. Instead, as shown in Figure 1 of Gelbard, the distal surface of connecting member 36 does not even touch, much less bear against, the proximal terminal end surface of first and second protruding members 22, 24. In fact, the first and second protruding members extend completely through connecting member 36, with their proximal terminal end surface left free. Thus, Gelbard has no element or structure that bears against or even touches the proximal terminal end surface of the protruding members, much less a distal surface of a connecting member that does so. Therefore, Gelbard fails to teach or suggest an express requirement of claim 1.

Accordingly, amended independent claim 1 distinguishes over Gelbard and represents allowable subject matter. Claims 4-35 are allowable at least because they depend from an allowable base claim.

Claim 56

Amended independent claim 56 recites a spinal fixation system that includes a first set of at least two bone anchors having a bone-engaging portion and a receiving portion with opposed arms that receive a fixation element therebetween. The system also includes a second set of at least one bone anchor and a fixation element disposable between the opposed arms of the receiving portion of the at least two bone anchors of the first set for connecting the bone anchors of the first set. The system further includes a connecting plate that connects a bone anchor of the first set with a bone anchor of the second set. The connecting plate has a distal surface that bears against a proximal terminal end surface of the opposed arms of the receiving portion of the bone anchor of the first set and a distal surface that bears against a proximal terminal end surface of the opposed arms of the receiving portion of the bone anchor of the second set. The system also includes a closure mechanism that extends through the connecting plate and engages one of the bone anchors to fix the fixation element within the bone anchor.

For the same reasons explained above with respect to claim 1, Gelbard fails to teach or even suggest a connecting plate having a distal surface that bears against a proximal terminal end surface of the opposed arms of the receiving portion of a bone anchor. In contrast, no structure in Gelbard even touches the proximal terminal end surface of the opposed arms.

Moreover, Gelbard lacks a closure mechanism that extends through the connecting plate and engages one of the bone anchors, as further required by claim 56. As shown in Figure 1 of Gelbard, the only structures that extend through the connecting member 36 are first and second protruding members 22, 24. If these protruding members were considered a closure mechanism, Gelbard would be lacking a receiving portion with opposed arms, as specifically required by claim 56. The first and second protruding members 22, 24 of Gelbard cannot form both the claimed opposed arms and the claimed closure mechanism. Further, since protruding members 22, 24 are themselves an integral part of the bone anchor, they can not be said to engage the bone anchor.

Accordingly, amended independent claim 56 distinguishes over Gelbard and represents allowable subject matter. Claims 57 and 59 are allowable at least because they depend from an allowable base claim.

Claim 60

Amended claim 60 recites a method of fixing vertebrae relative to each other. The method includes the step of implanting a first bone anchor and a second bone anchor in a first vertebra and a second vertebra, respectively and the step of connecting the first and second bone anchors with a fixation element. The method also includes the step of positioning a distal surface of a connecting plate on a proximal terminal end surface of opposed arms of a rod receiving portion of the first bone anchor by inserting a closure mechanism through the connecting plate to engage the rod receiving portion.

As discussed above with respect to claims 1 and 56, Gelbard fails to teach or even suggest positioning a distal surface of the connecting member on a proximal terminal end surface of the opposed arms of the rod receiving portion of the bone screw. Instead, the opposed arms of Gelbard pass all the way through the connecting member and no contact is made between the connecting member and the proximal terminal end surfaces of the opposed arms.

Further, as discussed above with respect to claim 56, Gelbard lacks a closure mechanism and thus fails to disclose a further requirement of the claimed method. Claim 60, as well as claims 61-63 which depend therefrom, therefore distinguish over Gelbard and represent allowable subject matter.

***Claim Rejections Pursuant to 35 U.S.C. § 103(a)***

Claims 4-11, 15, and 16 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of U.S. Patent No. 5,522,816 ("Dinello"). Claims 12-14 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of Dinello and in further view of U.S. Publication No. 2004/0087949 ("Bono"). Claims 30-33, 57, and 58 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of U.S. Publication No. 2004/0186474 ("Matthis"). Claims 21-27 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of U.S. Patent No. 5,366,455 ("Dove"). Claims 34, 35, and 59 are rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of Matthis and further in view of Dinello. Claim 28 is rejected pursuant to 35 U.S.C. § 103(a) as being obvious over Gelbard in view of Dove and further in view of U.S. Patent No. 6,355,038 ("Pisharodi").

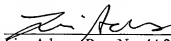
None of the secondary references cited by the Examiner can be relied on to render independent claims 1, 56, or 60 obvious as no person having ordinary skill in the art would modify Gelbard to have a connecting plate with a distal surface that bears against a proximal terminal end surface of opposed arms of a receiving portion of a bone anchor. Gelbard is specifically directed to a plate having openings that receive the rod receiving portion of the bone screw therethrough to allow a closure mechanism to be applied to the rod receiving portion. If the distal surface of the connecting plate were modified to bear against the proximal terminal end of the opposed arms of the rod receiving portion, the closure mechanism could not be mated to the rod receiving portion. As a result, the device would be inoperative as there would be no way to lock the connecting plate to the bone anchor. Claims 1, 56, and 60, as well as the claims that depend therefrom, therefore distinguish over Gelbard in view of the various references cited by the Examiner, and thus represent allowable subject matter.

#### ***Conclusion***

Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested. Applicants' amendment of the claims does not constitute a concession that the claims are not allowable in their unamended form. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Date: *Nov. 19, 2007*

Respectfully submitted,



Lisa Adams, Reg. No. 44,238  
Attorney for Applicant(s)

Nutter McClennen & Fish LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
Tel: (617) 439-2550  
Fax: (617) 310-9550